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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,165	08/05/2003	Nancy T. Chang	223695	6346

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,165	CHANG ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Applicant should note that this application, which claims a priority of August 22, 1984, appears to have no viable patent term since it is already more than 20 years from the priority date.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 19-21, 32, 34, drawn to HIV polypeptide sequences, classified in class 530, subclass 350.

II. Claims 10-18, 22-27, drawn to nucleic acid sequences, classified in class 536, subclass 23.1.

III. Claims 28-31, 33, drawn to methods of production of proteins, classified in class 435, subclass 69.1.

IV. Claims 35-38, 43, 45, 48, drawn to antibodies, classified in class 530, subclass 387.1.

V. Claims 39-42, 44, drawn to immunoassays, classified in class 435, subclass 7.1.

VI. Claims 46-47, drawn to nucleic acid assays, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

3. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids,

and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide of group I. For example, as disclosed in the specification, claim 2 requires the env polypeptide, whereas the nucleic acid molecule of claim 17 requires only a portion of the protein. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. For example, a nucleic acid which is "essentially homologous" as in claim 18, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with the disclosed protein. In addition, while a polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group II, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one

where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 17 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of groups I and II together.

4. Inventions in Group I and in Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein could be made by the recombinant method of Group III or by chemical synthesis or by purification from the natural source.

Searching the inventions of Groups I and III together would impose serious search burden. The inventions of Groups I and III have a separate status in the art as

shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of production of HIV polypeptides are not coextensive. Group I encompasses molecules which are claimed in terms of homology and immunoreactivity, which are not required for the search of Group V. In contrast, the search for group V would require a text search for the method of synthesis of HIV polypeptides in addition to a search for the protein sequences. Prior art which teaches a polypeptide which is homologous to the disclosed HIV sequences would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide product were known, the method of synthesis which makes the product may be novel and unobvious in view of the preamble or active steps.

5. The polypeptide of group I and the antibody of group IV are patentably distinct for the following reasons:

While the inventions of both group I and group IV are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of group I and group IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group IV. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

6. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used as detection marker as in Group V or in synthesis of antibodies or in enzymatic reactions such as reverse transcriptase based methods (since the claims encompass the HIV RT enzyme).

Searching the inventions of Groups I and V together would impose serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the

polypeptides and the method of detection of HIV using a polypeptide are not coextensive. Group I encompasses molecules which are claimed in terms of homology and immunoreactivity, which are not required for the search of Group V. In contrast, the search for group V would require a text search for the method of detection of HIV in addition to a search for the protein sequences. Prior art which teaches a polypeptide which is homologous to the disclosed HIV sequences would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide product were known, the method of detection which uses the product may be novel and unobvious in view of the preamble or active steps.

7. Inventions I and VI are unrelated because the product of group I is not used or otherwise involved in the process of group VI.

8. Inventions II and either III or V are unrelated because the product of group I is not used or otherwise involved in the process of group III or V.

9. The polynucleotide of group II and the antibody of group IV are patentably distinct for the following reasons. The antibody of group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid

sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group III, and the antibody of group IV cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group IV would impose a serious search burden since a search of the polynucleotide of group II would not be used to determine the patentability of an antibody of group IV, and vice-versa.

10. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group II can be used to make recombinant proteins, in nucleic acid purification methods, in nucleic acid amplification methods, or in microarray expression analysis methods as opposed to its use in detection of HIV.

Searching the inventions of Groups II and VI together would impose serious search burden. The inventions of Groups II and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of detection of HIV using a polynucleotide are not coextensive. Group II encompasses molecules which are claimed in terms of

homology in regard to reference sequence shown in the figures, which are not required for the search of Group V. In contrast, the search for group V would require a text search for the method of detection of HIV in addition to an oligonucleotide search of fragments of the disclosed HIV sequences. Moreover, even if the polynucleotide product were known, the method of detection using the product may be novel and unobvious in view of the preamble or active steps.

11. Inventions III, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting HIV using an antibody (group V), the method of detecting HIV using a polynucleotide (group VI), and the method of making HIV polypeptides (group III) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection of HIV differ significantly for each of the materials. For detection using the polynucleotide, hybridization may be used. For detection using the antibody, quantitation of labeled antibody may be used. For synthesis of the polypeptide, the polypeptide is expressed by a cell which has the nucleic acid of interest. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups III, V and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV, V and VI together.

12. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to treat HIV, to purify HIV virus or proteins from a source or used in the detection method of Group V.

Searching the inventions of Groups IV and V together would impose serious search burden. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the method of detection of HIV using an antibody are not coextensive. Group IV encompasses molecules which are claimed in terms of binding to HIV. In contrast, the search for group V would require a text search for the method of detection of HIV in addition to a search for antibodies which bind HIV. Moreover, even if the antibody product were known, the method of diagnosis which uses the product may be novel and unobvious in view of the preamble or active steps.

13. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed

product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Election

15. Claims 1-48 are generic to a plurality of disclosed patentably distinct species comprising each of the HIV open reading frames. For example, claim 1 is generic to every HIV protein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. This species should consist of a particular HIV open reading frame for examination, for example one of Gag, Pol, etc. as disclosed in figure 1 and in the specification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
5/25/05